MAY 1 7 2000

K000812

II. 510(k) SUMMARY

Submitted by: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

Contact Person: David B. Jones

Date Prepared: February 25, 2000

Proprietary Name: NEURO SCAN MEDICAL SYSTEMS
Model Nos.: 302L Medicor (Laboratory)
302P Advantage 3000 (Portable)

Common Name: EMG/EP System

Classification Name: Diagnostic Electromyography /
Evoked Response Electrical Stimulation System

Predicate Device: Advantage EMG/EP systems (K885246 and K973355, Attachment 1)

Device Description: The Neurosoft Medicor and Advantage 3000 EMG/EP systems' device descriptions have not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems' device descriptions. The Neurosoft Medicor and Advantage 3000 are systems for Diagnostic Electromyography and Evoked Response Electrical Stimulation. The Neurosoft Medicor and Advantage 3000 EMG/EP systems work in the same manner as the approved and predicate device.

Intended Use: The Neurosoft Medicor and Advantage 3000 EMG/EP systems' intended use has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems. The Neurosoft Medicor and Advantage 3000 EMG/EP systems diagnose disorders of the nervous and muscular systems.

Technological Characteristics: The Neurosoft Medicor and Advantage 3000 EMG/EP systems' technological characteristics have not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems. The Neurosoft Medicor and Advantage 3000 EMG/EP systems' has the same technological characteristics as the approved and predicate device.

III. Labeling

The Neurosoft Medicor and Advantage 3000 EMG/EP systems' labeling has changed. Changes include system name, responsible party and address, and sales and marketing address. The user manual has been updated to include a tutorial. These are the only labeling changes from the labeling approved under K973355. Attachments 2, 3, 4 and 5 contain revised package labeling, promotional literature, the operating and service manual, and web page, respectively.

IV. Description

The Neurosoft Medicor and Advantage 3000 EMG/EP systems' description has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems.

V. Substantial Equivalence

The Neurosoft Medicor and Advantage 3000 EMG/EP systems' substantial equivalence to its predicate device has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems.

VI. Manufacturing

The Neurosoft Medicor and Advantage 3000 EMG/EP systems' manufacturing and location have changed. The Neurosoft Medicor and Advantage 3000 EMG/EP systems' manufacturing facility physical and mailing address 5700 Cromo Drive, Suite 100, El Paso, TX 79912, and our Establishment Registration Number is 1650946.

In addition, Neurosoft has changed selected Medicor and Advantage 3000 EMG/EP systems' components to replace obsolete parts and increase manufacturability (attachment 6, Hardware CAPA List). Component changes were evaluated for performance and safety characteristics and meet or exceed the original equipment manufacturer's performance and safety characteristics.

VII. Electrical Safety

The Component changes were evaluated for electrical safety and meet or exceed the original equipment manufacturer's electrical safety. Neurosoft Medicor and Advantage 3000 EMG/EP systems' electrical safety has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems.

VIII. Performance Measurement

The Component changes were evaluated for performance measurement and meet or exceed the original equipment manufacturer's performance measurement. The Neurosoft Medicor and Advantage 3000 EMG/EP systems' performance measurement has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems.

IX. Biocompatability

The Neurosoft Medicor and Advantage 3000 EMG/EP systems' biocompatability has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems.

X. Software

The Software Component was evaluated for performance to the original manufacturer's specifications. Several potential errors were determined (bugs) and corrective/preventive actions implemented (attachment 7, Software CAPA List). The Software Component meets the original equipment manufacturer's performance specification. The Neurosoft Medicor and Advantage 3000 EMG/EP systems' software has not changed from the Telemetrix-CME's Advantage Medical EMG/EP systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2000

Mr. David B. Jones
Regulatory Affairs and
Quality Assurance Manager
Neurosoft, Inc.
5700 Cromo Drive
Suite 100
El Paso, Texas 79912

Re: K000812
Trade Name: Neuro Scan Medical Systems
Model Numbers: 302L Medico (Laboratory)
302P Advantage 3000 Portable
Regulatory Class: II
Product Code: IKN
Dated: March 10, 2000
Received: March 13, 2000

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Applicant: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

510(k) Number: K 000812

Device Name: Neurosoft **Advantage A3000/Medicor** system

Indications For Use: The Neurosoft **Advantage A3000/Medicor** is a Diagnostic Electromyography/Evoked Response Electrical Stimulation (EMG/EP) System designed for the monitoring and analysis of electromyography data. A variety of electrophysiologic tests can be performed to determine whether disease of peripheral nerves or muscle is present in adult and pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000812

Prescription Use X or Over-the-Counter _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)